

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNIVERSITY OF WESTERN AUSTRALIA)	
SAREPTA THERAPEUTICS, INC., and)	
SAREPTA INTERNATIONAL C.V.)	
)	
Plaintiffs,)	
)	C.A. No. _____
v.)	
)	
ACADEMISCH ZIEKENHUIS LEIDEN,)	
BIOMARIN PHARMACEUTICAL, INC., and)	
BIOMARIN NEDERLAND B.V.,)	
)	
Defendants.)	

COMPLAINT

Plaintiffs University of Western Australia, Sarepta Therapeutics, Inc. and Sarepta International C.V., by and through their attorneys and for their Complaint against Defendants Academisch Ziekenhuis Leiden, BioMarin Pharmaceutical, Inc. and BioMarin Nederland B.V., state and allege as follows:

NATURE OF THE ACTION

1. This is an action under 35 U.S.C. § 146 to review and correct the rulings of the Patent Trial and Appeal Board (the “PTAB”) of the United States Patent and Trademark Office (the “PTO”) in Interference No. 106,013 (the “’013 Interference”) between U.S. Patent No. 8,486,907 (“the UWA ’907 patent”) assigned to Plaintiff University of Western Australia and U.S. Patent Application Serial No. 14/198,992 assigned to Defendant Academisch Ziekenhuis Leiden, including the Decision on Motions (Paper No. 192) (copy attached as Exhibit A), the Order to Show Cause (Paper No. 193) (copy attached as Exhibit B), the Decision on Priority (Paper No. 196) (copy attached as Exhibit C), Judgment (Paper No. 197) (copy attached as Exhibit D) and the Decision on Rehearing (Paper No. 202) (copy attached as Exhibit E), and to

decide all issues that were before the PTO in the '013 Interference and which should have been decided in the '013 Interference.

THE PARTIES

2. Plaintiff University of Western Australia ("UWA") is an academic institution of the state of Western Australia, having a principal place of business at 35 Stirling Highway, Crawley, Australia 6009.

3. UWA has exclusively licensed rights in the UWA '907 patent to Plaintiff Sarepta Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 215 First Street, Cambridge, Massachusetts 02142, and to Plaintiff Sarepta International C.V., having a principal place of business at Fred. Roeskestraat 123, 1076 EE Amsterdam, Netherlands ("collectively "Sarepta").

4. On information and belief, Defendant Academisch Ziekenhuis Leiden ("AZL"), is an academic institution of the Netherlands, having a principal place of business at Albinusdreef 2, 2333 ZA Leiden, Netherlands.

5. On information and belief, Defendant AZL exclusively licensed rights in U.S. Application Serial No. 14/198,992 ("the AZL '992 application") to Prosensa Technologies B.V., which has been acquired by Defendant BioMarin Pharmaceutical, Inc. ("BioMarin"), a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 770 Lindero Street, San Rafael, California 94901.

6. On information and belief, on or about April 27, 2015, the name of Prosensa Technologies B.V., was changed to that of Defendant BioMarin Nederland B.V., having a principal place of business at J.H. Oortweg 21, 2333 CH Leiden, Netherlands.

JURISDICTION AND VENUE

7. This court has subject matter jurisdiction pursuant to 35 U.S.C. § 146¹ and 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(c).

FACTS COMMON TO ALL COUNTS

9. UWA is the owner of the UWA '907 patent. The exclusive licensee of the UWA '907 patent, Sarepta, has the power and right to prosecute the application which issued as the UWA '907 patent, as well as the power and right to contest interferences involving the UWA '907 patent.

10. AZL is the owner of the AZL '992 application. On information and belief, BioMarin has the power and right to contest interferences involving the AZL '992 application.

11. The United States Patent and Trademark Office Patent Trial and Appeal Board ("PTAB") declared the '013 Interference between the UWA '907 patent and the AZL '992 application on September 29, 2014. The Declaration of Interference ("the Declaration"; Paper No. 1) indicated that the subject matter of the '013 Interference related to the subject matter

¹ Plaintiffs believe that, under a proper reading of the Patent Act, the Court has jurisdiction over this case pursuant to 35 U.S.C. § 146. Plaintiffs are aware that the May 7, 2015, decision of the U.S. Court of Appeals for the Federal Circuit in *Biogen MA, Inc. v. Japanese Foundation for Cancer* (Case No. 2014-1525) may be read as precluding this Court's jurisdiction. However, Biogen filed a Petition for a writ of *certiorari* on November 9, 2015 (Docket No. 15-607), and hence this issue has not been finally decided. Indeed, if left undisturbed, the Federal Circuit decision in Biogen "will deprive parties to pending and future interferences of unique benefits available only in district court under § 146." (December 10, 2015 Brief *amicus curiae* of Sarepta Therapeutics, Inc., at p. 9). If relief under Section 146 is unavailable, then in the interests of justice this case should be transferred to the Federal Circuit under 28 U.S.C. § 1631. *In re Teles AG, Informationstechnologien*, 747 F.3d 1357 (Fed. Cir. 2014).

involved in Interferences 106,007 (“the ’007 Interference”) and 106,008 (“the ’008 Interference”).

12. The UWA ’907 patent issued from U.S. Application Serial No. 13/270,992, filed October 11, 2011, which is a continuation of U.S. Application Serial No. 12/837,359, filed July 15, 2010, which is a continuation of U.S. Application Serial No. 11/570,691, filed January 15, 2008 and issued as U.S. Patent No. 7,807,816 (“the UWA ’816 patent”), which is one of the UWA patents involved in the ’008 Interference.

13. The UWA ’816 patent is directed to antisense oligonucleotides against exon 51 of the dystrophin gene, while the UWA ’907 patent is directed to methods of inducing skipping of exon 51 of the dystrophin gene using antisense oligonucleotides against exon 51, which correspond to the antisense oligonucleotides of the UWA ’816 patent.

14. The AZL ’992 application is a continuation of U.S. Application Serial No. 13/550,210, filed July 16, 2012 (“the AZL ’210 application”), which is the AZL application involved in the ’008 Interference.

15. The AZL ’210 application is directed to antisense oligonucleotides against exon 51 of the dystrophin gene, while the AZL ’992 application is directed to methods of inducing skipping of exon 51 of the dystrophin gene using antisense oligonucleotides against exon 51, which correspond to the antisense oligonucleotides of the AZL ’210 application.

16. The Declaration proposed a Count that was Claim 1 of the AZL ’992 application or Claims 1, 19, 22 or 25 of the UWA ’907 patent, and designated all of Claims 1-31 of the UWA ’907 patent and all of Claims 1-27 of the AZL ’992 application as corresponding to the Count.

17. The Declaration required UWA to file a motion (1) showing why at least one claim of the UWA '907 patent interfered with at least one claim of the AZL'992 application; (2) explaining why UWA would prevail on priority; and (3) providing a chart showing where each of UWA's applications for which benefit has been accorded provide a constructive reduction to practice of the Count. (Paper No. 1, 2:22-3:8). Administrative Patent Judge Richard E. Schafer was designated to manage the interference. (Paper No. 1, 3:13-15).

18. The Declaration indicated that "[t]he only motion authorized is UWA's motion discussed above. The filing of additional motions will be evaluated at a later date." (Paper No. 1, 3:20-22).

19. UWA filed its Motion (Paper No. 133) on November 18, 2014, addressing all of the issues the Board required of it, including that UWA would prevail in the interference because none of AZL's applications either in the interference or for which they were granted priority, provided written description or enablement for the claims in the AZL '992 application, noting that UWA should "be entitled to proceed with an interference if it can "prove at least so much of its case as would entitle it to an award of priority if the senior party were to rely only on its filing date and were not to rebut any of the junior party's case.'" *Brown v. Fodor*, Interference No. 104,358, Paper No. 60 at p. 2 (BPAI 1999). (Paper No. 133, 6:13-14:9). AZL opposed (Paper No. 148) and UWA replied (Paper No. 152).

20. The PTAB issued a Decision on Motions (Paper No. 192) finding that AZL disclosed at least one embodiment within the scope of the Count in its March 21, 2003 International Application PCT/NL2003/000214. The PTAB also maintained that UWA's cited precedent for relying on AZL's failings under 35 U.S.C. § 112(a) as a basis for continuing in the interference did not address the issue of "undue breadth" as asserted by UWA against AZL.

(Paper No. 192, 8:17-9:14). As such, the PTAB also issued an Order to Show Cause (Paper No. 193) on June 22, 2015, requiring UWA to prove it was entitled to a date prior to March 21, 2003.

21. UWA filed its Response to the Order to Show Cause on July 20, 2015 (Paper No. 194), arguing that unpatentability under 35 U.S.C. § 112(a) is an appropriate basis to establish priority, and should be taken up as a threshold issue. (Paper No. 194, 4:8-6:16). UWA also argued that the outcome of the '013 Interference should be made contingent on the outcome in the '008 Interference, because AZL's claims in both interferences defined the same subject matter, and hence, doing so would provide judicial efficiency as well as consistent results. (Paper No. 194, 6:17-11:15; 14:14-16:20). UWA also argued AZL's claims in the '013 Interference should be barred under 35 U.S.C. § 135(b) just as UWA argued AZL's claims were barred in the '008 Interference, that UWA had not had an opportunity to brief that issue in the '013 Interference, and that the issue should be resolved consistently with the '008 Interference and as a threshold issue. (Paper No. 194, 11:16-14:13).

22. On September 29, 2015, the PTAB issued its Decision on Priority (Paper No. 196) and Judgment ("the Judgment"; Paper No. 197) in favor of AZL, holding that 37 C.F.R. § 1.608(b), which allowed a junior party to remain in an interference if it could show that it was *prima facie* entitled to a *judgment* relative to the senior party, had been superseded by 37 C.F.R. § 41.202(d), which requires that the junior party must show why it would prevail on *priority*. (Emphasis in original; Paper No. 197, 6:21-9:14). The Judgment further ordered the cancellation of the UWA '907 patent in its entirety.

23. UWA filed a Request for Rehearing on October 29, 2015 (Paper No. 198), again arguing that the issues of 35 U.S.C. § 112(a) and 35 U.S.C. § 135(b) were threshold issues that

must be addressed in order to determine that AZL had standing to be in the '013 Interference.

The PTAB denied the Request for Rehearing on December 29, 2015, admitting that

the summary procedure used here against [UWA] is not expressly covered by the rules governing interferences, [but] those rules also provide that

[t]he Board may determine a proper course of conduct in a proceeding for any situation not specifically covered by this part and may enter non-final orders to administer the proceeding.

(Paper No. 202, 8:12-18).

24. The PTAB also held that AZL would still have standing to prove prior invention in the interference even if its claims were unpatentable under 35 U.S.C. § 112(a) and/or barred under 35 U.S.C. § 135(b). (Paper No. 202, 9:26-10:11).

25. In deciding the '013 Interference on the sole basis of UWA's ability to prove prior invention for the invention claimed in the '013 Interference, the result in the '013 Interference may be inconsistent with the result in the '008 Interference, resulting in one party having claims to particular antisense oligonucleotides (the party prevailing in the '008 Interference), while the other party would have claims to methods of using those same oligonucleotides (the party prevailing in the '013 Interference).

CLAIMS FOR RELIEF

COUNT I

26. UWA hereby incorporates paragraphs 1-25 above as if set forth in full herein.

27. Pursuant to 35 U.S.C. § 146, UWA has elected to file suit in this Court to review and reverse the PTAB's Decision on Motions, Order to Show Cause, Decision on Priority and Judgment, and to decide all issues raised before the PTAB. UWA has not sought review of the

Board's Decision by the United States Court of Appeals for the Federal Circuit².

28. The PTAB erred in effectively canceling UWA's issued '907 patent claims without considering the issue of whether AZL had standing to contest the interference, by refusing to consider whether AZL's claims are unpatentable under 35 U.S.C. § 112.

29. The PTAB erred in effectively canceling UWA's issued '907 patent claims without considering the issue of whether AZL had standing to contest the interference, by refusing to consider whether AZL's claims are barred under 35 U.S.C. § 135(b).

PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations and claims, Plaintiffs UWA, Sarepta Therapeutics, Inc. and Sarepta International C.V., respectfully request that the Court enter judgment in its favor and award it the following relief:

30. Reversing the PTAB's Decision on Motions (Paper No. 192), which refused to consider that UWA was *prima facie* entitled to judgment relative to AZL, because AZL's claims are unpatentable under 35 U.S.C. § 112(a), and allowing UWA to present evidence for this Court to decide the issue, or alternatively, remanding the issue to the PTAB and directing the PTAB to allow UWA to file, and to substantively consider, a motion that the claims in the AZL '992 application are unpatentable under 35 U.S.C. § 112(a).

31. Reversing the PTAB's Decision on Priority (Paper No. 196), which refused to consider that UWA was *prima facie* entitled to judgment relative to AZL, and that AZL lacked standing in the Interference, because AZL's claims are unpatentable under 35 U.S.C. § 112(a)

² UWA reserves the right subsequently to file a protective notice of appeal to the Federal Circuit (see, e.g., *fn1, supra*) in order to preserve its right to appellate review in the event the *Biogen* decision is not modified, and any subsequent filing is not a waiver of Plaintiff's right to proceed with the present action under Section 146, in the event the *Biogen* decision is vacated or modified.

and barred under 35 U.S.C. § 135(b), and allowing UWA to present evidence for this Court to decide the issues, or alternatively, remanding the issues to the PTAB and directing the PTAB to allow UWA to file, and to substantively consider, a motion that AZL's claims in the '013 Interference are unpatentable under 35 U.S.C. § 112(a) and a motion that AZL's claims in the '013 Interference are barred under 35 U.S.C. § 135(b).

32. Reversing the PTAB's Decision on Rehearing (Paper No. 202), wherein the PTAB "decline[d] to exercise [their] discretion to decide patentability" and refused to consider that AZL lacked standing in the Interference, because AZL's claims are unpatentable under 35 U.S.C. § 112(a) and barred under 35 U.S.C. § 135(b), and allowing UWA to present evidence for this Court to decide the issues, or alternatively, remanding the issues to the PTAB and directing the PTAB to allow UWA to file, and to substantively consider, a motion that AZL's claims in the '013 Interference are unpatentable under 35 U.S.C. § 112(a) and a motion that AZL's claims in the '013 Interference are barred under 35 U.S.C. § 135(b).

33. Allowing UWA to present evidence for this Court to decide, or alternatively, remanding the issue to the PTAB and directing the PTAB to allow UWA to file, and to substantively consider, a motion that AZL's claims in the '013 Interference are unpatentable under 35 U.S.C. § 112(b), consistent with the motion submitted by UWA in the '008 Interference.

34. Reversing the PTAB's entry of judgment against UWA on any and all grounds that the Court finds appropriate, including, but not limited to, the fact that it constitutes a "taking" under the U.S. Constitution, Amendment 5.

35. Directing the PTAB to concurrently and consistently consider the issues in the '013 and '008 Interferences.

36. Directing the United States Patent and Trademark Office to cancel Claims 1-27 of the AZL '992 application.

37. Directing the United States Patent and Trademark Office to reinstate Claims 1-31 of the UWA '907 patent.

38. Awarding Plaintiffs their costs and attorneys' fees in this action, and such other and further relief as this Court deems just and proper.

Respectfully submitted,

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